IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: Tobin Island, et al.

Application No.: 10/783,880 Group Art Unit: 3739

Filed: February 19, 2004 Examiner: Henry M. Johnson III

Title: SELF-CONTAINED, EYE SAFE HAIR-REGROWTH INHIBITION APPARATUS AND METHOD

Rule 132 Declaration of Professor Joseph W. Goodman

Joseph W. Goodman declares and states as follows:

1. I am a Professor Emeritus of Electrical Engineering at Stanford University. As shown on my attached resume, I headed the Electrical Engineering Department at Stanford University from 1988 to 1996, when I assumed the position Senior Associate Dean for Faculty and Academic Affairs in the School of Engineering. I served as the President of the Optical Society of America in 1992, and I am the author of several books on optics. A significant portion of my career has been focused on holography, synthetic aperture optics, image processing, and speckle theory. I am very familiar with the effects of diffusers on various light sources, including lasers and laser diodes.

2. I have no financial interest in the outcome of this matter, nor do I have any prior relationship with Spectragenics or any of the inventors of the above-named patent application. I am being compensated for my time at my normal consulting rate.

3. I have made an extensive review of Dr. Michael Slatkine's patent application no. WO 03-049633 (the "'633"). The '633 shows a fundamental misunderstanding of optical physics, particularly with regard to the effect of diffusers on laser light sources. Many of the designs described in the '633 are not only not 'eye safe', but instead mislead the reader into believing that a device built according to the teachings of the '633 would be eye safe when in fact that device would be extremely dangerous to the eye, and particularly the retina.

4. A fundamental error in the '633's teachings is at page 9, in the last sentence of the first full paragraph, where Dr. Slatkine states that:

> "As referred to herein, monochromatic light is defined as being divergent when its exit angle from the distal end of the monochromatic light source, or from the distal end of a diverging unit, when used, is greater than a half angle of 6 degrees, wherein a"half angle"is defined as the half angle measured on a plane perpendicular to the propagation axis of a collimated beam generated by the monochromatic light source. With such a divergent angle, protective eyeglasses having an optical density approximately of only 2 are required for the aesthetc [sic] laser types specified hereinafter, corresponding to a transmittance of 1%. When the divergent half angle is 20 degrees, protective eyeglasses with an optical density of 1 are required, corresponding to a transmittance of 10%. <u>When the divergent half angle is 60 degrees, no protective eyeglasses are required.</u>" [Emphasis added.]

The underlined statement is wrong as a matter of optical physics. Lasers, whether laser diodes or other forms of lasers, emit spatially coherent light. Except for very low power lasers, operating at very low fluences, it is not possible to achieve eye safety merely by increasing the divergence of monochromatic, i.e., laser, light to 60 degrees. Instead, the light (1) must be made spatially incoherent, and (2) must have a sufficiently low fluence. The basic concept is that, as long as the lens of the eye can re-image the light source on the retina as something approaching a point source, the risk of retinal damage exists and the device is not eye safe except at very low power levels. As used in this context, "spatially incoherent" means that the lens of the eye cannot re-image the light source to a small enough spot on the retina that it will damage the eye.

5. This same fundamental misunderstanding occurs again in the description of Figure 14, found at page 38, where the '633 states:

> "Figure 14 illustrates another preferred embodiment of the invention in which a diffusing unit is not used, but rather a diverging optical element is employed to produce an exit beam having radiance, or alternatively, energy density, depending on the wavelength, below a safe level."

This statement is, again, simply wrong as a matter of physics. Merely using a diverging element, such as a lens, does not render the light source spatially incoherent even if the divergent element results in a half angle of 60°, and does not make it eye safe. If one of ordinary skill in the art were to follow these teachings of the '633, they would believe that they had built an eye-safe device,

but in fact that device would be extremely dangerous at fluences sufficient to remove hair. This same conceptual error is repeated in the discussion of Figure 14A, where the divergent element 741 is a simple convex lens. At page 38, the '633 states:

> "When divergent beam 742 has a cross sectional dimension at least equal to cross section 752, its radiance is less than an eye safe level."

Again, following this teaching of the '633 would result in a device which is dangerously unsafe to the retina of the eye at any fluences used by Dr. Slatkine in his examples that perform hair removal.

6. The device illustrated in Figure 14b of the '633 suffers from a similar misconception, and would not yield an eye safe device at any reasonable fluences. Figure 14b and the associated description, found at page 40, describes an array of reflective lenslets with convex reflectors. The lenslets 992 have a reflective coating 993 on their back side, so that they serve as a divergent reflector. The light reflected through the lenslets 992 strikes a plurality of convex reflectors 995. The rays then exit through transparent plate 994. The intent is to achieve "a safe radiance level" by producing a "divergent half angle of 60 degrees." Again, this shows a complete misunderstanding of what is required to achieve eye safety. The elements of Figure 14b merely provide divergence. There is no diffusive element at all, and therefore the spatial coherence of the laser source is not destroyed, and the resulting output will not be eye safe. In some respects, the lenslet array of 14b presents even greater risk of eye injury, because each of the lenslets essentially results in a point source that is unsafe, so that, instead of just one unsafe beam, the design of Figure 14b yields an array of unsafe beams.

7. A related misconception about eye safety is found at page 32 of the '633, where the device of Figure 8b is described as

> "diffuser 784 produces a small diffusing angle of T2, and refractive/reflective element 785 expands angle T2 to achieve wide diffusing angle T."

A diffuser with a small diffusing angle is essentially a poor diffuser, and so the teaching of '633 is that a poor diffuser, combined with a refractive/reflective element (i.e., a lens or a mirror) can yield an eye safe device. This is simply not true. The use of the diffuser with a small half angle makes the beam only slightly less coherent. The addition of a lens or mirror only spreads out the beam, it does not make it less coherent. The device of Figure 8b would product multiple extended virtual sources, each one of which could be imaged to a small spot on the retina, and would not be eye safe at fluences sufficient to perform a dermatological procedure such as removing hair.

8. The misconception that merely diverging light is the same as diffusing it is repeated at page 49, second paragraph, of the '633, where it states:

> "As can be seen from the above description, a diffusing/diverging unit of the present invention, which is mounted to the exit aperture of a conventional laser unit, induces the exit beam to be divergent/and or scattered at a wide angle. As a result the exit beam is not injurious to the eyes and skin of observers, as well as to objects located in the vicinity of the target."

9. This misconception is perpetuated in the last paragraph on page 40 of the '633, where the supposedly eye-safe designs are summarized as follows:

> In summation, the present invention incorporates four groups of units which cause a monochromatic light to diverge at a sufficiently wide angle so that the radiance of an exit beam is eye safe:
>
> 1) A diverging unit provided with a single diverging optical element;
>
> 2) A multi-component diverging unit provided with reflective and refractive optical elements, and without any diffusers;
>
> 3) A diffusing unit provided with a single thin diffusively transmitting element; and
>
> 4) A multi-component diffusing unit, whereby a wide divergent, diffusing angle is achieved by using a high thermally resistant refractive/reflective optical component, as well as at least one thermally resistant low angle diffuser.

In fact, contrary to the statements made in the '633, there is no disclosure in the '633 that teaches how to make an eye safe device using any of these units, if the powers are more than a small fraction of a watt.

10. At page 45 of the '633, Table I provides a number of examples that are said to be 'eye safe' if the number in the bottom row exceeds 1. Thus, the examples titled "Non coherent Diode based", and both "Non coherent Nd:YAG based" examples are described as eye safe. However, the table provides values for only an <u>ideal</u> diffuser; see page 44, where it states:

Table I below presents a comparison in terms of eye safety between the exit beam of monochromatic light after being scattered by a diffusing unit into a solid angle of 3.14 sr, which is equivalent to that attained by an ideal transmitting diffuser, according to the present invention. The

The presentation of numbers for an <u>ideal</u> case is not helpful unless there is also disclosure of how to build an ideal diffuser. Nowhere in the '633 is there any such disclosure. In contrast, it is well known in the field that commercially available diffusers typically have lower half-angles than the ideal. This is true, as well, for the diffusers that the '633 actually discloses; none of the disclosed diffusers is perfect.

11. It should be noted that the '633 teaches nothing about the characteristics of a diffuser, nor does the '633 provide any meaningful guidance to enable one of ordinary skill in the art to build a diffuser to achieve a particular half angle. This omission is a critical defect, because in my opinion one of ordinary skill in the art would not know how build a diffuser with a particular half angle, nor would they know how to deal with less than perfect diffusers, nor would they know how to deal with the implications of using such imperfect diffusers. The only diffusers taught by the '633 are surface diffusers, rather than volume (or bulk) diffusers, and the only examples given in the '633 are relatively poor diffusers with small half-angles. In most cases, the half-angles are ten or 15 degrees, and the best example provides a half-angle of 40 degrees.

12. The '633 provides no guidance which would enable one of ordinary skill in the art to balance the conflicting objectives of achieving an optical output which is eye safe, while at the same time being of sufficient fluence to effect a dermatological procedure such as the removal of hair. Stated differently, nothing in the '633 makes it obvious to one of ordinary skill in the art how to construct an apparatus that uses a light source with sufficient fluence to effect hair removal on a human, and also has an optical diffuser for diffusing the light so that the light emitted from the apparatus is eye safe. Further, while the '633 mentions the use of a light guide, it is not inherent in a light guide that the output is uniformly distributed.

13. I have reviewed the Rule 132 Declaration of Dr. Gary C. Bjorklund being submitted in this matter, including the portions which describe the techniques used by Dr. Bjorklund to model the optical behavior of the devices described in the '633. In my opinion, the "Equivalent Extended Source" approach and the "Subaperture" approach are equally valid, and the correlation of the results achieved by each approach is well within reasonable limits.

14. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false

statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing therefrom.

Joseph W. Goodman

Date: May 14, 2007

Joseph W. Goodman

RESUME OF JOSEPH W. GOODMAN

Joseph W. Goodman received the A.B. Degree in Engineering and Applied Physics from Harvard University in 1958, and the M.S. and Ph.D. degrees in Electrical Engineering from Stanford University in 1960 and 1963, respectively.

From 1958 through 1962, he was a Research Assistant in the Stanford Electronics Laboratories. During 1962 and 1963, he was a post-doctoral Fellow at the Norwegian Defense Research Establishment, under the auspices of the Royal Norwegian Society for Scientific and Industrial Research. He returned to Stanford in 1963 as a Research Associate, a position he held until 1967, when he was appointed Assistant Professor of Electrical Engineering at Stanford. He was promoted to Associate Professor in 1969 and to Professor in 1972. In 1988 he was appointed Chairman of the Department of Electrical Engineering and named the William E. Ayer Professor of Electrical Engineering. In 1996 he stepped down as Chairman and assumed the position Senior Associate Dean for Faculty and Academic Affairs in the School of Engineering. For the duration of the Summer of 1999, he served as Acting Dean of Engineering. Prof. Goodman assumed Emeritus status on January 1, 2000.

During the academic year 1973-1974 he was a Visiting Professor at the Intitut d'Optique in Orsay, France. In the summer of 1984 he was the William Girling Watson Traveling Scholar at Sydney University, Sydney, Australia.

Dr. Goodman has held a number of positions of responsibility in the optics community. For the Optical Society of America (O.S.A.), he has served as a Traveling Lecturer, as Vice Chairman and Chairman of the Technical Group on Information Processing, as a member of the Technical Council, as a member and Chairman of the Fellows Committee, and as a member of the Ives Award Committee. He was elected a Director-at-Large of the OSA for the years 1972-1974; he also served on the Board of Directors ex-officio while he was Chairman of the Publications Committee, and while he was Editor of the Journal of the Optical Society of America (1978-1983). He was elected Vice President of the OSA for 1990, served as President Elect in 1991, President in 1992, and Past President in 1993. He currently serves as a member of the Nominating Committee and as a member of the Board of Directors of the OSA Foundation.

For the Society of Photo-Optical Instrumentation Engineers (S.P.I.E.), he was elected to the Board of Governors for the years 1980-1982, and has served as a member and Chairman of the Awards Committee, as a member of the Nominating Committee, and as a member of the Technical Council. He also served a second term as an elected Governor of the society for the years 1988-1990.

For the Institute of Electrical and Electronics Engineers (I.E.E.E.), he chaired an ad hoc Committee on Optical and Electro-Optical Systems in 1969, has served on the Editorial Board of the Proceedings of the I.E.E.E. for the years 1979 and 1980, and has been a member of the Education Medal Committee for 1987-1989.

His international activities include membership on the program committees for a large number of international meetings. He was a member of the U.S. delegation to the first and second U.S.-Japan Seminars on Optical Data Processing and Holography, and a member of the U.S. delegation to the first U.S.-U.S.S.R. seminar on optical data processing. In 1979 he chaired the U.S. delegation to the first U.S.-Argentina Seminar on Fourier Optics. In 1984 he was elected to a three-year term as Vice President of the International Commission for Optics (ICO), a commission affiliated with the International Union of Pure and Applied Physics (IUPAP). He served as President of the ICO for the years 1988-1990, and Past President for 1991-1993.

He has served as a Director of several corporations, including Optivision, Inc. (for which he was a co-founder), ONI Systems (for which he was the founding Chairman of the Board), and E-TEK Dynamics . He served on the Board of Directors for Ondax, Inc. from its founding until December 2004, and until recently served as the Chairman of the Board of Nanoprecision Products, Inc., a company he co-founded. He also serves on Technical Advisory Committees for several small private photonics companies.

The research contributions for which Dr. Goodman is best known are (1) his pioneering work on the statistical properties of speckle patterns, carried out in the early 1960's, (2) his contributions to holography and optical information processing through the 60's, 70's and 80's, and (3) his leadership in the 90's of a group that first proposed the use of optics for solving interconnect problems in VLSI systems, a topic of much current interest.

Dr. Goodman is a Fellow of the OSA, the IEEE, and the SPIE. In 1971, he was chosen recipient of the F.E. Terman award of the American Society for Engineering Education. He received the 1983 Max Born award of the Optical Society of America, for his contributions to physical optics, and in particular to holography, synthetic aperture optics, image processing, and speckle theory. He received the 1987 IEEE Education medal for his contributions to Electrical Engineering education, the 1987 Dennis Gabor Award of the International Optical Engineering Society (SPIE) for his contributions to holography, optical processing and optical computing, the 1995 Esther Hoffman Beller Education medal of the OSA, and the 1990 Frederick Ives Medal, the highest award of the Optical Society of America. He was a member of the National Academy of Engineering in 1987, and a Fellow of American Academy of Arts and Sciences in 1996. Also in 1996, he received an honorary D.Sc. degree from the University of Alabama. He is the recipient of the 2007 Gold Medal of the S.P.I.E., that society's highest award. He is the author of approximately 220 technical publications, including the textbooks Introduction to Fourier Optics (1968, Second Edition, 1996, Third Edition 2005); Statistical Optics (1985); (with R.M. Gray) Fourier Transforms: An Introduction for Engineers (1995); and Speckle Phenomena in Optics: Theory and Applications (2005). His first full-length publication (Proc. I.E.E.E., Vol. 53, 1688 (1965)) was named a "Citation Classic" by the Institute for Scientific Information.